

STATES DISTRICT COURT  
NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545
IN RE: ABBVIE, INC., PRODUCTS LIABILITY LITIGATION  This Document Relates to All Cases	Master Docket Case No. 1:14-cv-01748  Hon. Judge Matthew F. Kennelly

**DEFENDANTS' SUPPLEMENTAL BRIEF IN SUPPORT OF THEIR PROPOSED  
PRODUCTION FORMAT**

In a sharp departure from the weight of authority and the default practice in many courts across the country, Plaintiffs insist on seeking a production of all file types in native format. At the June 9 hearing, the Court ordered Defendants to submit additional briefing regarding the additional burden and expense of making their productions entirely in native format. As a threshold, the Federal Rules of Civil Procedure provide that the producing party is entitled to choose the format for production. As such, Defendants' election to produce in TIFF with load files and electronic text should govern, absent some exigency which does not exist here. In fact, producing in native format would cause a significant burden and added expense *to all parties* in ensuring that the integrity of documents is not compromised, and in referencing and reconciling any varying copies of documents. The complexities in reviewing and preparing productions in

native format would also greatly increase Defendants' burdens and expenses and significantly slow the pace of discovery.

**A. TIFF Productions Are Widely Used And Accepted**

Defendants propose to produce all documents – other than unredacted spreadsheets and audio and video files<sup>1</sup> – in standard Tagged Image File Format (“TIFF”), along with extracted text and load files containing agreed-upon metadata fields. Under this production format, Defendants would produce TIFF images that each bear a Bates number stamp and confidentiality designation where appropriate. Along with the stamped images, Defendants would produce load files and electronic extracted text that allow Plaintiffs to organize and search the documents however they want. With this format, Plaintiffs would have access to all of the relevant, non-privileged information they seek. Although Plaintiffs argued in their brief that a TIFF production would not allow them to receive comments in a PDF file or tracked changes in a Word document [*see* Plaintiffs' Memorandum of Points and Authorities Regarding ESI (“Pl. Memo”, p. 5)], this is wrong because a TIFF production is composed of images similar to a copy printed from the user's computer.

Defendants' proposed approach is fully consistent with the Federal Rules of Civil Procedure. As stated by the Court at the June 9 hearing, the Federal Rules of Civil Procedure allow a producing party to choose their format for production, as long as the production is made in the format “in which it is ordinarily maintained or in a reasonably usable form.” FED. R. CIV. P. 34(a)(1)(A); FED. R. CIV. P. 34(b)(2)(D) & (E)(ii). Neither the Advisory Rules nor the Sedona Conference Principles mandate any particular format for the production of ESI or metadata. *See*

---

<sup>1</sup> Defendants have already agreed to produce these specific files in native format because they have special features that cannot be reflected in a TIFF image, such as calculations in an Excel spreadsheet and audio-video features in an MPEG or WMV file.

also *In re Biomet M2A Magnum Hip Implant Products Liability Litigation* (MDL 2391), 2013 WL 1729682, \*2-3 (N.D. Ind. 2013) (holding that defendant Biomet's procedures for review and production complied fully with the requirements of the Federal Rules of Civil Procedure, and accordingly, "I can't find that the likely benefits of the discovery proposed by the [Plaintiffs'] Steering Committee equals or outweighs its additional burden on, and additional expense to, Biomet.").

As discussed previously in Defendants' Brief in Support of Their ESI Protocol, TIFF productions are the most widely used and universally accepted production format<sup>2</sup>, due to its many advantages. This production format has been accepted and adopted in MDL proceedings in other district courts. *See In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, MDL 1871, Dkt. 111 (E.D. Pa. Apr. 10, 2008); *In re Zolof Products Liability Litig.*, MDL No. 2342 (E.D. Pa.). Defendants have made considerable investment in their processes and data management systems designed to make electronic discovery as reliable and cost efficient as possible. Defendants have already agreed to Plaintiffs' detailed requests for extracted text and specifically formatted metadata load files, which will give Plaintiffs the ability to search quickly and efficiently through the documents electronically. With this format, the content of documents in both production formats is the same. Unlike native productions, however, Defendants' proposed TIFF production is not prone to the unintentional alteration after production, is simpler to number and reference, and is more effective for review and redactions.

Accordingly, Defendants should be permitted to make their productions in their proposed format.

---

<sup>2</sup> From an informal poll of several reputable electronic discovery vendors across the country, the answer was unanimous that over 90% of productions are generally made in TIFF.

**B. Native Format Productions Are More Difficult To Manage And Use, Creating A Significant Amount of Additional Burden On All Parties Including The Court**

Native productions are more difficult and burdensome to manage and use than TIFF productions for several reasons.<sup>3</sup> First, their content and metadata can be unintentionally modified by any party handling the documents, and all parties would be required to spend additional effort and time to ensure the reliability of documents. Second, copies of produced documents may not always be identical, and all parties would be required to spend additional effort and time to reference and reconcile different versions of the same document. Third, the review and redaction process in anticipation of native productions would take significantly longer and be more burdensome than for a TIFF production, because of the many complexities associated with in preparing native documents for production. The issues and burdens identified here will be exponentially troublesome for this matter, as this litigation involves several defendants with an expectation that each defendant will be producing significant volumes of ESI.

**1. Parties Using Native Productions Would Be Required To Spend Extra Effort, Time, and Expense to Verify That Documents Were Not Unintentionally or Unknowingly Altered**

TIFF productions are valuable because they preserve the integrity of documents. Because TIFF productions contain snapshots of documents as they were at the time of collection and processing, they provide an unalterable image for review, at depositions, and for the court. Static images are not susceptible to the risk of unintended alteration and thus are simpler and more efficient to manage. Over the course of any large litigation, a single document will likely be handled by numerous individuals using different devices and review platforms. Because native files are not “read-only,” the substance and metadata of native files can be inadvertently

---

<sup>3</sup> See Electronic Discovery Reference Model website, EDRM Framework Guides, Production Guide, 3. Identify Production Requirements, 3.1.1 Native File Formats, *available at* <http://www.edrm.net/resources/guides/edrm-framework-guides/production> (comparing the pros and cons of producing in native format).

altered by any party who handles the file. *See* Sedona Principles, 2. How is Discovery of Electronically Stored Information Different?, C. Dynamic, Changeable Content (“Electronically stored information can be modified in numerous ways that are sometimes difficult to detect without computer forensic techniques. Moreover, the act of merely accessing or moving electronic data can change it.”).

For example, if an individual unintentionally re-saved a document – even without making any changes – it could alter the document’s “Date Modified” metadata. If an individual highlighted a portion of a document and then unknowingly hit a stray key, it could delete that portion of the document. If an individual attempted to open an outdated file type and his software required him to convert the file type before the document could open, this could alter the file extension of the document, and possibly also the formatting and contents of the document.

Defendants do not believe that anyone would intentionally alter documents, but these are a few examples of plausible everyday scenarios where documents produced in native format could be unintentionally and unknowingly altered. To confirm that produced documents marked as exhibits at deposition or in trial are identical to what was originally produced, the parties would have to do a side-by-side comparison of both documents. Whereas TIFF images could be compared quickly by any lay person in trial or deposition, an electronic comparison of native documents can be difficult and require a technical expert, causing all parties (including the Court) to spend a significant amount of additional time, effort, and expense to verify documents. *See In Re Priceline. Com Inc. Sec. Litig.*, 233 F.R.D. 88, 91 (D. Conn. 2005). There would also be additional challenges to authenticating and comparing the metadata of each document.

**2. Parties Using Native Productions Would Be Required To Spend Extra Effort, Time, and Expense to Reference The Same Document And Reconcile Varying Copies of That Document**

Unlike TIFF productions, native files cannot receive bates numbers on each page. This is extremely problematic because all parties – including witnesses and the Court – cannot use the traditional and easy way to reference a certain page in a particular production. In a “native to native” production, where raw files are turned over without any additional processing, there would be no simple way to identify or pull a specific document. Parties preparing for deposition or trial could print documents for use as exhibits, but those copies would not have any identifying information for parties to ensure that the printed version is the same as the one that was produced. Searching electronically by file name would not be useful or effective where it is highly likely in a large litigation that documents have the same file name, and it would not be feasible to pinpoint the exact version without conducting additional searches through document text or metadata fields.

In Plaintiffs’ Memorandum of Points and Authorities Regarding ESI, Plaintiffs conceded that native files cannot accommodate bates stamps, but they argued that “it is commonplace to instead adopt an identifying ‘control’ number for the native document, which can be displayed in any subsequently printed image if necessary.” Pl. Memo, p. 6. Even if it were technically possible to open each native document and insert a repeating footer or header containing that document’s identifier on each page of the document, this would require a manual process multiplied over millions of pages that would likely consume thousands of hours of manpower to perform, thereby greatly increasing the cost of producing documents. Moreover, this does not resolve the difficulty of not having a paginated production defined with specific bates numbers on each page. If the parties wanted to refer to page 86 of a 200 page document that was not page

numbered, they would all have to manually count or flip through the document to find that page. This example presupposes that all parties even have a copy of the document with the same number of pages.

Even if manual pagination in native production were somehow possible (and that it did not alter the metadata of the file), Plaintiffs neglect to consider the fact that pagination in a full native production would likely be unreliable because it can change depending upon where and how the document was printed. Formatting and appearance of documents from native format productions can vary for individual users, depending on an individual's software and printer settings or even available fonts – and this variation can lead to a discrepancy in a document's total number of pages. As a result, all parties would have to spend added time and expense to reconcile and reference the same document. For example, some individuals use default margin settings, while others may have modified their settings to allow for bigger or smaller margins. Some individuals use default header and footer margins, while others may have modified their settings to allow for bigger or smaller headers or footers. Some types of printers allow for a greater printable area for documents than others. Some individuals may have access to particular types of fonts that are not universally used. As a result, depending on which individual printed the document and his or her software and printer settings, a particular sentence on page 55 of a 100 page document could turn out to be on page 72 of a 130 page document with identical content but different formatting – discovered only after a manual side-by-side comparison.

With varying versions of printed documents used in deposition or at trial, the process of reconciling the documents and referencing a particular page would be time consuming, unwieldy, and frustrating for all parties (including the Court). In contrast, TIFF productions can be automatically stamped with sequential bates numbers without the need for a person to

manually open and modify every document; thus a produced page in a sequentially numbered TIFF production could be easily referenced by all parties using its identifying bates number without question.

**3. The Preparation of Native Productions Would Require Defendants To Spend Extra Effort, Time, and Expense to Review, Redact, and Process Documents**

Reviewing and preparing documents for production in native format – *i.e.*, Defendants’ review for responsiveness and privilege and redactions – can add substantial time and expense to the process because it is more complicated, unreliable, and expensive. Viewing a document in native format requires the use of that document’s original software application. To the extent Defendants use any proprietary or non-standard software, or even older software applications or original operating systems (such as older versions of Microsoft Word or email programs), parties would have to find and purchase licenses or copies of those programs and install them for each individual reviewer so the document could be opened and viewed. The time required to locate, purchase, load, and launch software to view each file type on multiple computers would slow down document review and production, require substantial additional manpower, and increase the costs and burdens on all parties. In contrast, documents for TIFF productions are generally converted uniformly into an image that all reviewers can view in a document review platform without the need for opening up each document using its corresponding software. This potential challenge of native productions is contemplated by the Sedona Glossary within its definition of “native format.” *See* Sedona Glossary, Definition of Native Format (“Because viewing or searching documents in the native format may require the original application (for example, viewing a Microsoft Word document may require the Microsoft Word application), documents may be converted to a neutral format as part of the record acquisition or archive process.”).



Redacting documents in native format is also extremely difficult and would require a substantial amount of additional time, manual effort, and expense in processing and review. *See Williams v. Sprint/United Management Company*, Civ. A. No. 03–2200–JWL–DJW, 2006 WL 3691604, at \*7 (D. Kan. Dec. 12, 2006) (denying motion to compel production in native, noting that “Defendant raises legitimate concerns about producing the transmittal emails with their attachments in their native format, including whether production in native format would permit the redaction or removal of privileged information in the transmittal e-mail or the attachment.”). Defendants must review the files they produce for information protected from disclosure by HIPAA, other federal and state privacy requirements and attorney-client privilege and work product protections. Plaintiffs appear to understand this, as they state in their brief that they are willing to consider a TIFF production of redacted documents. Pl. Memo, p. 7.

As a preliminary matter, redacting a document in native format would require opening the native version and deleting text, thereby altering the document’s metadata and contents. Accordingly, a reviewer cannot directly redact within a native document without altering the document metadata. To circumvent this, an identical copy of the document would have to be created, using a method and process that keeps all metadata intact. Reviewing and redacting hidden text would also be more difficult in a full native production. Whereas TIFF processing can uniformly uncover hidden text for review and production, processing different file formats in native could require different techniques for revealing hidden text for review and possible redaction. Assuming content could be displayed, reviewer attorneys would need to change or delete certain hidden text for redaction purposes using different software, increasing the number of hours required to perform these redactions. Because this is not a part of Defendants’ current

document review processes, Defendants would have to spend additional time and expense to develop and set up a new process.

Verification of redactions in native format would also pose a significant amount of difficulty and would slow down the pace of review and production. A reviewer would not be able to view and confirm previously redacted content without doing a side-by-side comparison with the original unredacted native file. If a reviewer wanted to unredact a document, the original text would have to be searched for and manually pasted in, or a new copy of the document would have to be created. Notably, if both the redacted copy and unredacted copy were produced, all parties would not have any way of knowing from the printed copies that this was the same document produced twice with different redactions, as opposed to two different documents. The manual side-by-side comparison would also have to be used for logging privileged documents. In contrast, redactions made on TIFF images can be clearly marked and denoted in a way that does not alter the file itself, and can be easily further analyzed and modified by subsequent reviewers. These complexities in reviewing and making redactions in native files would greatly increase the burdens and expenses for review and redactions, slow the pace of discovery significantly, and very likely increase the rate of error.

Lastly, native format productions do not allow the documents to be marked appropriately for confidentiality. If a document with "Confidential" in its file name was printed in hard copy format, third parties who receive those printed copies would not know that they are looking at a document designated as "Confidential." Parties could not manually insert a "Confidential" footer onto the printed version of a produced document without altering the properties of the file itself. Even assuming a footer could be manually inserted without altering metadata, third parties receiving printed copies would have no way of knowing whether the "Confidential" designation

was part of the original document or whether it was inserted by the parties in the litigation. The ability to clearly designate each page of a confidential document as “Confidential” is especially important in this case, where Defendants will be producing sensitive business information. Confidentiality is also a concern for parties receiving emails in native format – *i.e.*, where the email is opened as a .MSG file in a reviewer’s own email software – could unintentionally forward the email to someone or send a “reply” to all of the parties listed on the email.

Even with a proper protective order in place, there is an increased risk of an unauthorized disclosure of a confidential document that does not have any confidentiality markings.

### **CONCLUSION**

From the outset of the discovery process, Plaintiffs have sought to impose burdens on Defendants that are neither justified by logic nor permitted by law. As discussed above, Defendants’ proposed TIFF production – with extracted text files and corresponding load files with captured metadata – will be fully searchable and just as usable for Plaintiffs as a native format production. Plaintiffs have no basis for demanding that Defendants produce their entire production in native format, and such an unreasonable demand could result in significant production delays and added expense. Plaintiffs’ unarticulated need for native files, along with the many disadvantages of a native production, do not outweigh the additional burden, time and expense to Defendants, or the potential alterability and unreliability of documents used in native format. A production made in TIFF strikes a fair balance that accounts for the practicalities of pagination, document presentation at trial and depositions, and protection from inadvertent alteration, while completely accommodating Plaintiffs’ concerns regarding readability and usability.

Accordingly, Defendants respectfully request that this Court permit them to make their productions in the format they have proposed.

Dated: July 7, 2014

Respectfully submitted,

REED SMITH LLP

By: /s David E. Stanley  
David E. Stanley (*pro hac vice*)  
Janet H. Kwuon (*pro hac vice*)  
**REED SMITH LLP**  
355 S. Grand Avenue, Suite 2900  
Los Angeles, CA 90071  
Tel: (213) 457-8000  
dstanley@reedsmith.com  
*Attorneys for Eli Lilly and Company and Lilly USA LLC*

Thomas J. Frederick  
Scott P. Glauber  
Bryna J. Dahlin  
Nicole E. Wrigley  
**WINSTON & STRAWN LLP**  
35 West Wacker Drive  
Chicago, Illinois 60601  
Tel: (312) 558-5600  
Fax: (312) 558-5700  
sglauber@winston.com  
tfrederick@winston.com  
bdahlin@winston.com  
nwrighley@winston.com  
*Attorneys for AbbVie Inc. and Abbott Laboratories*

Andrew K. Solow  
**KAYE SCHOLER LLP**  
425 Park Avenue  
New York, NY 10022  
Tel: (212) 836-7740  
Fax: (212) 836-6776

Pamela J. Yates  
**KAYE SCHOLER LLP**

1999 Avenue of the Stars, Suite 1700  
Los Angeles, CA 90067  
Tel: (310) 788-1278  
Fax: (310) 788-1200  
*Attorneys for Endo Pharmaceuticals Inc.*

Tinos Diamantatos  
**MORGAN, LEWIS & BOCKIUS**  
77 West Wacker Drive, 5th Floor  
Chicago, IL 60601  
Tel: (312) 324-1145  
Fax: (312) 353-2067  
tdiamantatos@morganlewis.com

James D. Pagliaro (*pro hac vice*)  
Thomas J. Sullivan (*pro hac vice*)  
Ezra D. Church (*pro hac vice*)  
**MORGAN, LEWIS & BOCKIUS LLP**  
1701 Market Street  
Philadelphia, PA 19103  
Tel: (215) 963-5000  
Fax: (215) 963-5001  
jpagliaro@morganlewis.com  
tsullivan@morganlewis.com  
echurch@morganlewis.com  
*Attorneys for Auxilium Pharmaceuticals Inc.*

Loren Brown (*pro hac vice*)  
**DLA PIPER LLP**  
1251 Avenue of the Americas  
New York, NY 10020  
Tel: (212) 335-4500  
Fax: (212) 335-4501  
loren.brown@dlapiper.com

Matthew A. Holian (*pro hac vice*)  
**DLA PIPER LLP**  
33 Arch Street, 26th Floor  
Boston, MA 02110  
Tel: (617) 406-6000  
Fax: (617) 406-6100  
matt.holian@dlapiper.com  
*Attorneys for Pfizer, Inc. and Pharmacia & Upjohn Company LLC*

Joseph P. Thomas

Jeffrey F. Peck  
K.C. Green  
Jeffrey D. Geoppinger  
**Ulmer & Berne LLP**  
600 Vine Street  
Suite 2800  
Cincinnati, OH 45202  
Tel: (513) 698-5000  
Fax: (513) 698-5001  
jthomas@ulmer.com  
jpeck@ulmer.com  
kcgreen@ulmer.com  
jgeoppinger@ulmer.com  
*Attorneys for Actavis, Inc., Actavis Pharma,  
Inc., Ando, Inc., and Watson Laboratories,  
Inc., a Nevada corporation*

**CERTIFICATE OF SERVICE**

I, David E. Stanley, hereby certify that on July 7, 2014, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ David E. Stanley